REMARKS

INTRODUCTION

Continued examination and favorable reconsideration are respectfully requested.

Claims 1-17 and 19-85 remain pending in the application. Claim 18 was previously cancelled and claims 22-83 were previously withdrawn. Support for the amendments to the claims can be found throughout the present application including the specification, for example, in paragraphs [0030] - [0033] and paragraphs [0042] - [0051], in the drawings, and in the original claims.

Applicants have duly considered the rejections of the claims in the Office Action and provide the foregoing amendments and following remarks. The application is in condition for allowance. Entry of this amendment, reconsideration and prompt favorable action are respectfully requested.

Rejection of Claims Under 35 U.S.C. §112, Second Paragraph

The Office Action, at page 2, rejects claims 1-17, 19-21, and 84-85 under 35 USC §112, second paragraph, due to the phrase in claim 1 that each data cluster is associated with a discrete combination "selected from neither the first allele nor the second allele, the first allele alone, the second allele alone, and both the first allele and the second allele." Applicants respectfully traverse this rejection. Applicants submit that the meaning of this phrase is adequately clear. Applicants submit that by its own terms, this phrase enumerates a set of combinations of the first and second alleles which define the recited discrete combinations. Applicants point out that this language in facts lists the four exhaustive possible combinations of the first and second alleles, and that nothing is indefinite or unclear

about those enumerated combinations. To assist the Examiner and advance prosecution, applicants have, however, amended claim 1 to even more clearly recite features of "each data cluster identifying a unique allelic classification comprising one of a discrete combination of alleles selected from neither the first allele nor the second allele...." The rejection of claims 1-17, 19-21, and 84-85 is overcome. Reconsideration and withdrawal of the rejection are respectfully requested.

Rejection of Claims Under 35 U.S.C. §101

The Office Action, at page 3, rejects claims 1-17, 19-21, and 84-85 under 35 USC §101 failing to reflect statutory subject matter. The Office Action particularly asserts that the claims fail to recite subject matter having a "useful, concrete, and tangible result." Applicants respectfully traverse the rejection. Applicants respectfully submit that the method of claim 1 and claims 2-17, 19-21, and 84-85 clearly operates on physical entities, including features of "acquiring intensity information for a plurality of samples," the samples clearly representing tangible objects. Claim 1 recites further features of "outputting the allelic classification of each of the plurality of samples." Applicants respectfully submit that the activity of "outputting" the classification is also a tangible feature, since, among other things, an output can not be transmitted without a signal representing that output, the signal likewise being a concrete or tangible entity. To assist the Examiner and advance prosecution, applicants have, however amended claim 1 to even more particularly refer to "outputting the allelic classification of each of the plurality of samples to at least one of a user, a database, an application, and an instrument." The rejection of claims 1-17, 19-21, and 84-85 is overcome. Reconsideration

and withdrawal of the rejection are respectfully requested.

Rejection of Claims Under 35 U.S.C. §102(e)

The Office Action, at page 8, rejects claims 1, 5-9, 10-11, and 16 as being anticipated by U.S. Patent No. 6,703,228 to Landers et al. The rejection is respectfully traversed. Landers et al. does not disclose every feature of the invention as claimed, and therefore does not anticipate claims 1, 5-9, 10-11, and 16.

Claim 1 recites a method for of allelic classification, including features of "acquiring intensity information for a plurality of samples," and "evaluating at least the relationship between [the] first intensity component and the second intensity component for each of the plurality of samples to identify one or more data clusters." Claim 1 defines the nature of the identified data "clusters," including features that "each data cluster identif[ies] a unique allelic classification comprising one of a discrete combination of alleles selected from neither the first allele nor the second allele, the first allele alone, the second allele alone, and both the first allele and the second allele." Claim 1 thus recites specific characteristics regarding the recited "clusters," each cluster as identifying a discrete combination of alleles, those alleles being selected from enumerated combinations of the first and second alleles.

Claim 1 recites further features of "generating a likelihood model that predicts the probability that an allelic combination of a selected sample from the plurality of samples will reside within a particular data cluster of the one or more data clusters based upon the intensity information of the selected sample." Claim 1 includes additional features of

"applying the likelihood model to the intensity information of each of the plurality of samples to identify the associated allelic classification for each corresponding sample of the plurality of samples."

Claim 1 thereby includes features of predicting the probability via a likelihood model that a sample classification will fall into or reside in one of the clusters defining a unique allelic combination. This action is predictive, i.e., provides an estimate of a sample's associated cluster and therefore the sample's allelic classification, without *a priori* knowledge of the allelic combination present in that sample.

Landers et al. fails to describe a method for allelic classification as claimed. The Office Action, at page 6, asserts that Landers et al. "discusses determining allele frequencies of an SNP in a population, which represents identifying one or more data clusters that are associated with a discrete allelic combination." Applicants respectfully traverse the suggestion that Landers et al. identifies one or more data clusters in the fashion claimed. Claim 1 recites that "each data cluster identif[ies] a unique allelic classification comprising one of a discrete combination of alleles selected from neither the first allele nor the second allele, the first allele alone, the second allele alone, and both the first allele and the second allele." That is, the "data cluster" of claim 1 specifies or identifies a unique combination of alleles, selected from the enumerated set of combinations, as noted above.

Landers et al. fails to describe any identification action at the level of the alleles themselves. Applicants respectfully submit that Landers et al. teaches not any technique for separating or identifying the unique allelic combination of a sample determined by detected intensity components. Landers et al. instead merely discusses the probability

that a given allele (or SNP) is associated with a specific disease or phenotypical trait, at the aggregate level of population genetics. Landers et al. does not describe techniques for the identification of the alleles, themselves.

Landers et al. instead in fact simply assumes that the allelic combination associated with a trait or disease in a population is *a priori* known. The only "cluster" discussed in Landers et al. is at the level of a population cluster, at the level of disease or phenotype expression being linked with a known allele. If the allelic classification of a sample were not known, Landers et al. would provide no teaching whatsoever about how to determine it.

Landers et al. instead describes determining how a cluster of individuals with already-known alleles can correlate with overall patterns of traits or diseases- not how an unknown allelic combination can be discriminated or predicted, in the first place. Landers et al. therefore fails to describe "evaluating at least the relationship between [the] first intensity component and the second intensity component for each of the plurality of samples to identify one or more data clusters," those data clusters being defined according to the enumerated allelic categories. Landers et al. entirely fails to describe such an "evaluation" to arrive at the recited "data clusters," and fails to anticipate claim 1 for this reason, alone.

Landers et al. also fails to describe further features of claim 1, including "generating a likelihood model that predicts the probability that an allelic combination of a selected sample from the plurality of samples will reside within a particular data cluster." Landers et al. fails to describe any such predictive likelihood model that predicts the "probability of a selected sample from a plurality of samples will reside

within a particular data cluster," at all. The Office Action, at page 6, asserts that Landers et al. at "col. 31 and 32, discusses a likelihood model to predict the probability that a sample will have a particular disease classification or that particular data will be linked, which represents generating a likelihood model to predict probability that a sample resides within a particular cluster and determines a sample and its associated allelic composition."

Applicants respectfully traverse the suggestion that Landers et al. describes features of "generating a likelihood model that predicts the probability that an allelic combination of a selected sample from the plurality of samples will reside within a particular data cluster of the one or more data clusters based upon the intensity information of the selected sample," as recited in claim 1. What Landers et al. by its own terms describes is that "SNP analysis can be used to determine whether an individual has or will develop a particular phenotypic trait and whether the presence or absence of a specific allele correlates with a particular phenotypic trait." Landers et al., col. 31, lines 9-12. This describes a higher-order correlation between known SNPs and disease or phenotype expression, in a population. Landers et al. further states that it is "possible to identify SNPs which segregate with a particular disease. Multiple polymorphic sites may be detected and examined to identify a physical linkage between them or between a marker (SNP) and a phenotype." Landers et al. col. 31, lines 37-40. Applicants respectfully submit that this is not a description of "generating a likelihood model that predicts the probability that an allelic combination of a selected sample" will "reside within a particular data cluster," based on the "intensity information" of the sample. This is instead a description of determining how well a known SNP relates to a known

phenotype or disease expression, after the SNP is identified. The SNP correlation discussed by Landers et al. is, again, analyzed at the population level.

The SNP being discussed in Landers et al. is presumed to be known and is therefore not, and need not be, "predict[ed]" using a "likelihood model" that operates to predict that an "allelic combination of a sample" will "reside within a particular data cluster." Again claim 1 clearly defines that the data cluster is not any cluster of population or other data, but that the "data cluster identif[ies] a unique allelic classification comprising one of a discrete combination of alleles." Moreover, once a "likelihood model" is generated, claim 1 includes yet further features that of "applying the likelihood model to the intensity information of each of the plurality of samples to identify the associated allelic classification for each corresponding sample of the plurality of samples," an identification action that Landers et al. does not describe, since Landers et al. does not contemplate such a model.

Claim 1 therefore distinguishes over Landers et al. for the additional reasons that Landers et al. does not identically describe "generating a likelihood model" and "applying the likelihood model to the intensity information of each of the plurality of samples to identify the associated allelic classification for each corresponding sample," as further recited in claim 1. The rejection of claim 1 is overcome and should be withdrawn. Reconsideration is respectfully requested.

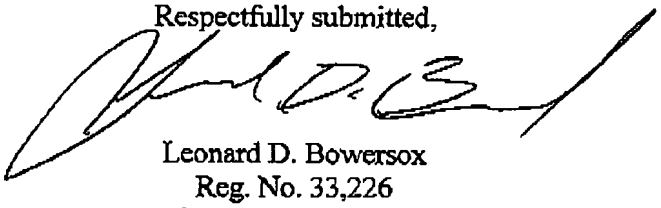
Claims 5-9, 10-11, and 16 distinguish over Landers et al. for at least the same reasons as claim 1, from which they depend. The rejection of claims 1, 5-9, 10-11, and 16 is overcome. Reconsideration and withdrawal of the rejection are respectfully requested.

CONCLUSION

In view of the foregoing remarks, Applicants respectfully request favorable reconsideration of the present application and a timely allowance of the pending claims.

Should the Examiner deem that any further action by Applicants or Applicants' undersigned representative is desirable and/or necessary, the Examiner is invited to telephone the undersigned at the number set forth below. If there are any other fees due in connection with the filing of this response, please charge the fees to deposit Account No. 50-0925. If a fee is required for an extension of time under 37 C.F.R. § 1.136 not accounted for above, such extension is requested and should also be charged to said Deposit Account.

Respectfully submitted,



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